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	TRANSMITTAL		Application Number	10/611,598		
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1	☐ Information Disclosure Stateme	<u> </u>				
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	Response to Missing Parts/ Incomplete Application					
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ŗ			OF APPLICANT, ATTORNEY	, OR AGENT		
		and Townsend a				
1	or Individual Scott L. Au	usenhus	Reg. N	No. 42,271		
	Signature	auen	Jul			
	Date II- 2	0-03				
1		CERTIFIC	CATE OF TRANSMISSION/M	MAILING		
ľ	I hereby certify that this correspondence i as first class mail in an envelope address	s being facsimile transied to: Commissioner	smitted to the USPTO or deposited wi for Patents, P.O. Box 1450, Alexandr	rith the United States Postal Service with sufficient postage ria, VA 22313-1450 on the date shown below.		
ľ		e M. Wartell				
ľ	Signature Date U-20-03					

Commissioner for Patents

20. Box 1450

Algandria, VA 22313-1450

November 20, 2003

TOWNSEND and TOWNSEND and CREW LLP

By:

Nicole M. Wartell

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Johannes B.M.M. van Bree

Application No.: 10/611,598

Filed: June 30, 2003

For: TREATMENT OF POMPE'S

DISEASE

Examiner: unassigned

Art Unit: unassigned

INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR §1.97 and

§1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. This application is a continuation of and relies upon U.S. Patent Application No. 09/454,711 for an earlier effective filing date under 35 U.S.C. §120. In accordance with 37 CFR §1.98(d), all of the references have been previously submitted to or cited by the Office in the parent application, and are therefore not enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Johannes B.M.M. van Bree et al. Application No.: 10/611,598

Page 2

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that <u>no fee is required</u> for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted

Scott L. Ausenhus Reg. No. 42,271

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Tel: 303-571-4000 Fax: 303-571-4321

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Substitute for form 1449A/PTO Complete if Known 10/611,598 **Application Number** INFORMATION DISCLOSURE Filing Date June 30, 2003 STATEMENT BY APPLICANT van Bree, Johannes B.M.M. First Named Inventor Art Unit unassigned (use as many sheets as necessary) **Examiner Name** unassigned 16994G-012730US Sheet of 3 Attorney Docket Number

			U.S. PATENT DO	CUMENTS+		
Document Number						
Examiner Initials*	Cite No. ¹	Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	A1	US-5,356,804	10-18-1994	Desnick et al.		
	A2	US-5,565,362	10-15-1996	Rosen		
	А3	US-6,118,045	09-12-2000	Reuser et al.		

				FOREIGN PA	TENT DOCUME	NTS	-	
Examiner	Cite	Foreign Patent Document		Dublication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant		
Initials*	No. ¹	Country Code ³	Number⁴	Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	T ⁶
	B1	PCT	WO 93/255	67 A	12-23-1993			
	B2	PCT	WO 97/055	71 A2	02-20-1997			

Examiner Signature	Date Considered	



Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	2	of	3

Complete if Known				
Application Number	10/611,598			
Filing Date	June 30, 2003			
First Named Inventor	van Bree, Johannes B.M.M.			
Art Unit	unassigned			
Examiner Name	unassigned			
Attorney Docket Number	16994G-012730US			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	C1	Barnes, Alison K. & Wynn, Colin H. "Homology of Lysosomal Enzymes and Related Proteins: Prediction of Posttranslational Modification Site Including Phosphorylation of Mannose and Potential Epitopic and Substrate Binding Sites in the a - and β -Subunits of Hexosaminidases, a -Glucosidase, and Rabbit and Human Isomaltase" <i>Proteins: Structure, Function, and Genetics</i> , 1988, Vol.4, pp.182-189.	
	C2	Belen'kii, D. M. et al. "Purification and Properties of Acid α-Glucosidase (γ-Amylase) from Human Liver." Translated from: <i>Biokhimiya</i> , Sept-Oct 1975, 40 (5) pp. 927-933.	
	СЗ	Bijvoet, Agnes G. A. et al., "Expression of cDNA-Encoded Human Acid <i>a</i> -Glucosidase in milk of Transgenic Mice," <i>Biochimica and Biophysica Acta</i> , Volume 1308, 1996, pp. 93-96.	
	C4	Bresciani, Roberto et al. "Lysosomal acid phophatase is not involved in the dephosphorylation of mannose 6-phosphate containing lysosomal proteins." <i>Eur. J. of Cell Biol. June</i> 1992, Vol. 58, No. 1, pages 57-61.	
	C5	de Barsy et al. "Enzyme Replacement in Pompe Disease: an Attempt with Purified Human Acid Alpha Glucosidase", Birth Defects Original Article Series, 9 (2) pp. 184-190 March 1973.	
	C6	Hoefsloot, Lies H. et al., "Expression and Routeing of Human Lysosomal <i>a</i> -Glucosidase in Transiently Transfected Mammalian Cells," <i>Biochemical Journal</i> , 1990, Volume 272, pp. 485-492.	
	C7	Houdebine, Louis-Marie "Production of pharmaceutical proteins from transgenic animals." <i>J. of Biotech.</i> , 1994, Vol. 34, pages 269-287, Elsevier Publishing.	
	C8	Kichuchi et al., "Clinical and Metabolic Correction of Pompe Disease by Enzyme Therapy in Acid Maltase-Deficient Quail", <i>J. Clin. Invest.</i> , 101 (4) pp. 827-833, February 1998.	
	C9	Minamiura, Noshi et al. "Identity of α-Glucosidase of Human Kidney with Urine F-1 α-Glucosidase." <i>J. Biochemistry</i> , 1982, Vol. 91, pages 809-816.	
	C10	Obara, Yoshiaki et al. "Mutual relationship between milk components and lysosome enzymatic activity in abnormal milk." <i>Japanese Journal of Veterinary Science</i> , 1983, Vol. 45, No. 2, pages 203-208.	
•	C11	Oberkotter, Linda V. et al. "N-acetyl-β-hexosaminidase activity in human breast milk." International Journal of Biochemistry, 1982, Vol. 14, No. 2, pages 151-154.	
	C12	Platenburg Gerard J. et al., "Expression of Human Lactoferrin in Milk of Transgenic Mice," <i>Transgenic Research</i> , 1994, Volume 3, pp. 99-108.	
	C13	Rochefort, Henri et al., "The Estrogen-Regulated 52K-Cathepsin-D in Breast Cancer: From Biology to Clinical Applications," <i>Nuclear Medicine and Biology</i> , 1987, Volume 14, No. 4, pp. 377-384.	
	C14	Van der Ploeg, A. T. et al., "Intravenous Administration of Phosphorylated Acid α -Glucosidase Leads to Uptake of Enzyme in Heart and Skeletal Muscle of Mice," <i>The Journal of Clinical Investigation</i> , February 1991, Volume 87, No. 2, pp. 513-518.	

Examiner	Date	
Signature	 Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.



Substitute for form 1449B/PTO Complete if Known INFORMATION DISCLOSURE Application Number 10/611,598 Filing Date June 30, 2003 STATEMENT BY APPLICANT First Named Inventor van Bree, Johannes B.M.M. Art Unit unassigned (use as many sheets as necessary) Examiner Name unassigned Sheet 3 of 3 Attorney Docket Number 16994G-012730US

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	C15	Van Hove et al., Purification of Recombinant Human Precursor Acid Alpha Glucosidase, Biochemistry and Molecular Biology International, 43 (3) pp. 613-623, October 1997.				

Examiner	Date	
Signature	Considered	

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